

Food and Drug Administration
Rockville MD 20857

JUN 28 1996

Re: Ultane™

Docket No. 95E-0302 **RECEIVED**

JUL 3 1996

**PATENT EXTENSION
/C PATENTS**

Ross C. Terrell, Ph.D.
Vice President of Research and Development
Inhalon Pharmaceuticals, Inc.
P.O. Box 21170
Lehigh Valley, PA 18002-1170

Dear Dr. Terrell:

This letter is in response to your December 20, 1995 letter which argues that the application for patent extension of Patent No. 4,250,334 based on the approval of Ultane™ (sevoflurane) is ineligible, because this patent claims a method of synthesis of the product, not a human or animal drug product, medical device, or food or color additive.

According to the May 12, 1987 Memorandum of Understanding between the Patent and Trademark Office and the Food and Drug Administration ("FDA") (52 Fed. Reg. 17,830), the U.S. Patent and Trademark Office is responsible for determinations of whether a product is eligible for patent extension based on the type of patent proposed for extension. In fact, FDA only issues notices of regulatory review period determinations when in response to requests from the Patent and Trademark Office. Because the FDA does not have responsibility in this aspect of patent extension, your request should be directed to the Patent and Trademark Office.

However, it may be of interest of you to reexamine 35 U.S.C. § 156(a), which provides that "[t]he term of a patent which claims a product, method of using a product, or a method of manufacturing a product" that claims a human or animal drug product, medical device, or food or color additive approved under the regulatory review period as defined in the Act, is eligible for patent extension under the Drug Price Competition and Patent Term Restoration Act of 1984.

Attached are copies of the regulations referenced above. While a copy of this letter and your original request will be sent to the Patent and Trademark Office, you must still file your request with that office for further consideration of this issue.

Sincerely,

Ronald L. Wilson, Director
Health Assessment Policy Staff
Office of Health Affairs

Attachments

cc: Henry D. Coleman
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